



December 18, 2014

Food and Drug Administration
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Rayner Intraocular Lenses Ltd.
Dr. Juliette E. Cook
Director of Quality and Regulatory Affairs
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United Kingdom

Re: K143307
Trade/Device Name: Raysert Plus Injector, Single Use Soft Tipped Disposable Injector
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: November 10, 2014
Received: November 24, 2014

Dear Dr. Cook:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR

Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose,
and Throat Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K143307

Device Name

Rayner RaySert PLUS Small Incision Single Use Soft-Tipped Injector (Model RSP01)

Rayner Single Use Soft-Tipped Disposable Injector (Model STW01)

Indications for Use (Describe)

The Rayner Injectors (Models STW01 and RSP01) are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary document has been prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: December 11, 2014

Subject Device

Trade Name: Rayner Injectors (Models STW01 & RSP01)
Classification Panel: Ophthalmic
Product Code: MSS
Common Name: Folders and Injectors, Intraocular Lens (IOL)
Classification Name: 21 CFR 886.4300
Device Class: Class I

Predicate Device

The predicate device is the Single Use Soft Tipped Disposable Injector (Model R-INJ-04), concurrence date March 27, 2014.

Device Description

The Rayner Injectors are devices for folding and delivering Rayner C-flex intraocular lenses (models 570C and 970C), and other IOLs indicating the use of the Rayner Injectors in their approved labeling into the eye. The Rayner Injectors consist of a syringe shaped body and nozzle, with a soft tipped plunger, and a loading bay closed in use with a mobile flap. The Rayner Injectors are sterile, disposable plastic devices, with a narrow diameter circular lumen through which the IOL can be introduced into the eye in a single continuous action. Rayner Injectors are designed for single use only.

Intended Use

The Rayner Injectors are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.

This is the same indication for use as the predicate device.

Comparison of Devices

Please see the table below for a comparison of the subject device to the predicates.

Characteristic	Predicate K132002 (Model R-INJ-04)	Subject Devices (Models STW01 & RSP01)
Indication for Use	The single use disposable injector (Model R-INJ-04) is intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of this injector in their approved labeling.	The single use disposable injectors (Model STW01 and RSP01) are intended to be used to compress and insert into the capsular bag only those intraocular lenses that allow the use of these injectors in their approved labeling.
Contraindications	<ol style="list-style-type: none"> 1. Vitreous in the anterior chamber. 2. Zonular insufficiency. 	<ol style="list-style-type: none"> 1. Vitreous in the anterior chamber. 2. Zonular insufficiency.
Materials	Barrel: Polypropylene Flap: Polypropylene Nozzle: Polypropylene Plunger tip: TPE, Santoprene Plunger shaft: Polypropylene Guide Bush (x 2): Polypropylene	Barrel: Polypropylene Flap: Polypropylene Nozzle: Polypropylene Plunger tip: TPE, Santoprene Plunger shaft: Polypropylene Guide Bush (x 2): Polypropylene
Primary Packaging (Tray)	Vacuum formed, blue tinted, transparent 760µm PETG L x W x D (mm): 165.0 x 55.0 x 23.5	Vacuum formed, blue tinted, transparent 760µm PETG L x W x D (mm): 184.0 x 55.0 x 24.25
Primary packaging (Lid)	Tyvek grid TG 7307 spun bonded polyolefin 75g/m ² grid pattern lacquer coating. L x W (mm): 184.0 x 55.0	Tyvek grid TG 7307 spun bonded polyolefin 75g/m ² grid pattern lacquer coating. L x W (mm): 184.0 x 55.0
Number of Uses	Single Use	Single Use
Sterility	Supplied Sterile	Supplied Sterile
Sterilization Method	Ethylene Oxide	Ethylene Oxide
Sterility Assurance Level	10 ⁻⁶	10 ⁻⁶
Shelf Life	5 Years	5 Years

Conclusion

The Rayner Injectors described in this submission are substantially equivalent to the predicate devices.